

IN THE DRAWINGS:

The attached sheets of drawings include changes to Figs. 8, 19, and 22. The attached Replacement Sheets, which include Figs. 8, 19, and 22, replace the original sheets including Figs. 8, 19, and 22.

In Fig. 8, the reference symbol "140" is replaced by the reference symbol --143--.

In Fig. 19, the reference symbol "144" is replaced by the reference symbol --130--.

In Fig. 22, the reference symbol "134" is replaced by the reference symbol --130--.

Attachment: Three Replacement Sheets

Three annotated sheets showing changes

REMARKS

Claims 14-17, 19, 22-26, and 28 are pending. Claims 14-16, 19, 22, and 24-26 have been amended. Claims 18, 20, 21, and 27 have been canceled. Claim 28 has been added.

The specification has been amended to correct several obvious typographical errors and inconsistencies. In particular in paragraph [0054], the reference symbol 140 was replaced by the reference symbol 143 because the reference symbol 140 refers to the outwardly extending knob 140 on the activation knob 112 as noted in paragraph [0056]. In paragraph [0059], the reference symbol 144 was replaced by the reference symbol 130, and in paragraph [0060], the term "rotator" was replaced by the term "activation knob" for antecedent basis for claim 23. In paragraph [0061], the reference symbol 134 was replaced by the reference symbol 130 because the reference symbol 134 refers to the stopper within the cartridge as noted in paragraph [0054], and the reference symbol 140 was replaced by the reference symbol 143 as noted above.

Figs. 8, 19, and 22 have been amended for similar reasons.

Claim 15 has been amended by deleting the phrase "slidably connected to the" for clarification. For example, paragraph [0053] states that the needle shield is connected to the needle shield link.

Claim 28 has been added. Support for claim 28 can be found at least in paragraph [0069].

Claims 16, 22, 23, 25, 26 stand rejected under 35 U.S.C. §112, second paragraph, for indefiniteness due to perceived lacks of antecedent basis for various terms. These rejections have been obviated by this Amendment, which has appropriately corrected the rejected claims, for example by changing dependency.

Claim 26 has been amended by adding the phrase "after ejecting the medicament", support for which can be found at least in paragraph [0062], and by replacing the phrase "the other side of" with the phrase "other side on the outer surface of the first tubular member", for adjusting its dependency to claim 25.

Accordingly, it is respectfully requested that the indefiniteness rejections be reconsidered and withdrawn.

Claims 14, 16, 17, and 19 stand rejected under 35 U.S.C. § 102(e) for anticipation by International Publication WO 2004/028598 to Karlsson ("Karlsson"), and claims 15 and 24-26 stand rejected under 35 U.S.C. § 103(a) for obviousness

over Karlsson. Claims 22 and 23 also stand rejected for obviousness over a combination of Karlsson and U.S. Patent No. 5,304,152 to Sams ("Sams"). These rejections should be reconsidered and withdrawn because Karlsson does not disclose and would not have suggested all the features of the claims arranged as in the claims, as amended.

For example, claim 14 has been amended by incorporating the features of claim 18, which has been canceled. Thus, Karlsson's area between grooves 45 and the threads on the drive rod are clearly not the same as the claimed outwardly extending stop members of the plunger.

As amended, independent claim 14 is clearer that there are two sets of outwardly stop members, a first set that cooperates with the ridges and protrusions on the inner surface of the first tubular member and a second set that cooperates with corresponding stop members arranged on the activation means and with a set of descending ledges arranged on the inner surface of the second tubular member. This arrangement is described in the application at various places, including paragraphs [0054], [0057], and [0064]-[0066], and Figs. 8, 10, and 22. Karlsson does not teach and would not have suggested such an arrangement.

Moreover, claim 14 has been amended to clarify that the dose activating means cooperates with the plunger's second set of outwardly extending stop members for holding the plunger and the spring means in a tensioned locked position. In contrast, Karlsson's mode selector is arranged to be turned and pushed or pulled by a user in order to select a proper mode for operating the device, and movement of the mode selector causes movement of a dose actuating sleeve, a lock sleeve, a lock nut, and a drive rod in turn because of a concentric circle structure of these elements. Therefore, Karlsson's mode selector and the claimed dose activating means are substantially different in both structure and function, and so Karlsson neither teaches nor would have suggested the claimed subject matters.

Karlsson's assembly of a lock nut surrounded by a lock sleeve and a dose actuating sleeve has little to do with the claimed first tubular member, which co-acts with other claimed components to perform certain functions using co-operating means arranged on the components. The co-operating means comprise mechanical members like ridges, protrusions, ledges, etc. that are not taught by Karlsson. The first tubular member is arranged to co-operate with the plunger and the needle shield unit so as to enable relative movement between them during priming (see, e.g.,

paragraphs [0059] and [0060]), injection (see, e.g., paragraph [0061]), and after injection (see e.g., paragraph [0062]). The first tubular member is a single element that can perform and control the function mentioned above and the design of the first tubular member can reduce the number of elements in the device. In contrast, Karlsson's "assembly of the lock nut surrounded by the lock sleeve and the dose actuating sleeve" comprises three different components, a dose actuating sleeve, a lock sleeve, and a lock nut, which does not conform with the claimed subject matter. In addition, Karlsson does not teach and would not have suggested that the lock nut, the lock sleeve, and the dose actuating sleeve can be merged into one component that can perform the same functions as the first tubular member in the present application.

With regard to Karlsson's dose nut 62, independent claim 14 has been amended to clarify that the second tubular member is rotationally locked to the dose activating means, and is arranged with a set of descending ledges on its inner surface, which surfaces co-operate with the plunger's second set of outwardly extending stop members for setting and delivering a certain preset dose. This arrangement is described in paragraphs [0054], [0064], and [0065] and in Fig. 22, among other places. Karlsson does not teach and would not have suggested such a second tubular member.

In view of the complete absence from Karlsson of many features recited in claim 14 and its dependent claims, as amended, the anticipation and obviousness rejections over Karlsson cannot stand, and so it is respectfully requested that those rejections be reconsidered and withdrawn.

With regard to the obviousness rejections of claims 22 and 23 over the combination of Karlsson and Sams, amended claim 22 and its dependent claim 23 refer to the first and second sets of stop members, a start position, and a protrusion that, with the other features defined by the claims, are neither taught nor would have been suggested by either Karlsson or Sams. Such arrangements are described in the application in paragraph [0061] and Fig. 25, for example. Accordingly, the rejections must be reconsidered and withdrawn because Karlsson and Sams in combination do not support a prima facie case of obviousness, which requires among other things, a teaching of all features of a rejected claim.

It is believed that this application is in condition for allowance, and a Notice of same is respectfully solicited. If the Examiner has any questions, the undersigned attorney may be telephoned at the number given below.

Potomac Patent Group PLLC
P.O. Box 270
Fredericksburg, VA 22404
Tel: 919 928 9979
Filed February 20, 2009

Respectfully submitted,

/Michael G. Savage/

Michael G. Savage
Registration No. 32,596